HFI-35 (redacted copy for Pub. Display)

U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
850 Third Avenue, Brooklyn, New York 11232
740
Telephone: [718] 340-7000 Ext. 5301

DEC 16 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Vaijinath Chakote, M.D.
Empire Medical Building Associates
of Rockaway, Inc.
88-20 Rockaway Beach Boulevard
Rockaway Beach, New York 11693

Re: 10-NYK-98

Dear Dr. Chakote:

Your facility was inspected on December 2, 1997 by a representative of the New York City Bureau of Radiological Health, acting in behalf of the Food and Drug Administration. This inspection revealed that your facility failed to comply with certain of the Quality Standards for Mammography (MQSA) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

The number of masses scored in the phantom image, produced by your [redacted] x-ray unit, was 1.5 and did not meet the required number. The minimum number required for masses is 3. This deficiency appeared under the Level one heading of your MQSA Facility Inspection Report, which was issued after the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliances that were listed on the inspection report provided to you at the close of the inspection. These are, measured darkroom fog exceeded 0.05 (the measured fog level was 0.12); and, there were no phantom image QC charts present.

We are taking this opportunity to remind you that you still need to provide the pending documents appearing in the report for [redacted] These are documents showing his inital and continuing experience interpreting mammograms, 40 hours of initial CME in mammography, and evidence of his initial 2 months full time training in mammography. If these documents are not forthcoming, they will be added as noncompliances and you will receive an amended inspection report citing them as such. You will still be responsible for correcting them.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and the FDA's regulations. You are responsible for investigating and determining the cause of the deficiencies that the inspection identified and promptly initiating corrective action.

If you fail to promptly correct these deficiencies, the FDA may without further notice initiate regulatory action. Under MQSA, the FDA may impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards; suspend or revoke a facility's FDA certificate for failure to comply with the Standards; seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that the FDA regulations do not preclude the City from enforcing its own mammography laws and regulations. In some cases, these requirements may be more stringent than the FDA's. When you plan your corrective action, therefore, you should consider the more stringent City requirements, if any.

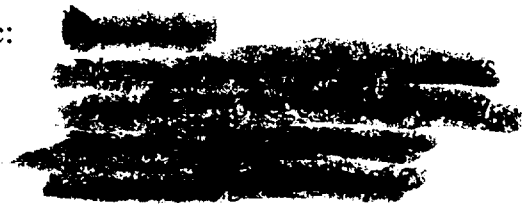
Within 15 working days after receiving this letter, you should notify the FDA in writing of the specific steps you have taken to correct the violations noted in this letter; each step your facility is taking to prevent a recurrence of similar violations; and, please submit records that demonstrate the corrections, including an acceptable phantom image. If your facility is unable to provide the requested documentation within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send your response to me at the above address, and a copy to Mr. Murray L. Kurzman, at US Food and Drug Administration, 6800 Jericho Turnpike, Suite 109E, Syosset, New York 11791. Also, send a copy to the City radiation control office that conducted the inspection referenced in this letter. You may choose to address both the FDA and City requirements in your response. If you have any questions regarding this letter or how to ensure you are meeting FDA standards, please call Mr. Kurzman at (516) 921-2035.

Sincerely yours,

Brenda J. Holman
District Director

BJH:mlk

cc: 

cc: Dorothy Pender
New York City Bureau of Radiological Health
2 Lafayette Street
New York, New York 10007